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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Application of
Troy M. Just
Serial No.: 10/668,785
Filed: September 23, 2003
Title: PRE-FILL APPLICATOR
Group No.: 3761

BEFORE THE BOARD
OF PATENT APPEALS
AND INTERFERENCES

Appeal No. _____

APPELLANT'S FOURTH AMENDED APPEAL BRIEF

Commissioner for Patents
Alexandria, VA 22313

Dear Sir:

REAL PARTY IN INTEREST

The Appellant has assigned all of his rights to the invention herein to HTI
Plastics; therefore, the real party in interest is HTI Plastics, Lincoln, Nebraska 68524.

RELATED APPEALS AND INTERFERENCES

There are no appeals or interferences related to this case.

STATUS OF THE CLAIMS

This is an appeal of the Examiner's final rejection of claims 1-3, 8, 10 and 11.
Claim 1 is an independent claim with claims 2 and 3 depending therefrom. Claim 8 is

1 an independent claim with claims 10 and 11 depending therefrom. Claims 1-3, 8, 10
and 11 are being appealed. Claims 4-7, 9 and 12-16 have been cancelled.

STATUS OF AMENDMENTS

5 The Examiner entered a final rejection of Appellant's claims on May 19, 2006.
Appellant did not file an Amendment After Final Rejection.

SUMMARY OF CLAIMED SUBJECT MATTER

10 Independent claim 1 describes a pre-fill vaginal applicator 10 (Fig. 2; p. 6, line
1) including a tubular barrel 16 (Fig. 9; p. 1, lines 3-8) having a dispensing end 20
(Fig. 9) provided with at least one opening formed therein and an open end 22 (Fig.
9). A selectively removable closure 12 (Figs. 2, 12, 13) or 14 (Figs. 19, 20; p. 6, lines
3-6) closes the dispensing end of the barrel when the applicator is not being used. A
15 resilient piston 62 (Figs. 3-5, 14, 15; p. 7, lines 18-22) is selectively slidably
positioned in the barrel 16 with the piston 62 having an outer surface which is in
sealing contact with the inner surface of the barrel 16 (Figs. 14, 15) to define a
medication reservoir 78 (Fig. 15; p. 8, lines 16-20). The second end of the piston has
an opening 68 (Fig. 3; p. 7, lines 21, 22, and p. 8, lines 1-5) extending thereinto
which terminates between the first and second ends of the piston 62. An elongated
20 plunger 48 (Fig. 6; p. 7, lines 12-20) is inserted into the open end of the barrel with
the first end of the plunger 48 being inserted into the opening 68 in the second end of
the piston 62 to detachably connect the plunger to the piston (Figs. 14, 15; p. 9, lines
9-17). The piston 62, prior to insertion into the barrel 16, has a larger outside
25 diameter than the inside diameter of the barrel 16 whereby the piston 62 is in a

1 compressed state against the inner surface of the barrel 16 when the piston 62 is
inserted into the barrel 16 (p. 9, lines 9-17). The plunger 48, when connected to the
piston 62 and moved towards the dispensing end of the barrel 16, causes the
resilient piston 62 to longitudinally stretch to permit the piston 62 to slide towards the
5 dispensing end of the barrel 16, thereby forcing medication in the medication
reservoir 78 to be ejected from the opening in the dispensing end of the barrel (Fig.
14; p. 9, lines 18-22, and p. 10, lines 1-7). The first end of the plunger 48 is
detachably connected to the piston whereby movement of the plunger 48 away from
10 the piston 62 will cause the first end of the plunger 48 to disconnect from the piston
62 so that the piston 62 remains in the barrel, thereby ensuring that the applicator
may not be reused (p. 9, lines 8-18).

15 Claim 2 depends from claim 1 and describes that the piston 62 has a portion
thereof shaped so as to be receivable within the opening formed in the dispensing
end of the barrel 16 (Figs. 3-5; p. 7, lines 21-22, and p. 8, lines 1-5).

20 Claim 3 is also dependent from claim 1 and describes that the piston 62 is
constructed so as to destruct if an attempt is made to manually move the piston 62
towards the open end of the barrel 16 by applying force against the first end thereof,
thereby further ensuring that the applicator may not be reused (p. 10, lines 8-18).

25 Independent claim 8 describes a vaginal applicator 10 (Fig. 2; p. 6, line 1)
including a tubular barrel 16 (Fig. 9; p. 1, lines 3-8) having a dispensing end 20 (Fig.
9) provided with at least one opening formed therein and an open end 22 (Fig. 9). A
resilient piston 62 (Figs. 3-5, 14, 15; p. 7, lines 18-22) is selectively slidably

1 positioned in the barrel 16 with the piston 62 having an outer surface which is in
sealing contact with the inner surface of the barrel 16 (Figs. 14, 15) to define a
medication reservoir 78 (Fig. 15; p. 8, lines 16-20). The second end of the piston has
an opening 68 (Fig. 3; p. 7, lines 21, 22, and p. 8, lines 1-5) extending thereinto
5 which terminates between the first and second ends of the piston 62. An elongated
plunger 48 (Fig. 6; p. 7, lines 12-20) is inserted into the open end of the barrel with
the first end of the plunger 48 being inserted into the opening 68 in the second end of
the piston 62 to detachably connect the plunger to the piston (Figs. 14, 15; p. 9, lines
10 9-17). The piston 62, prior to insertion into the barrel 16, has a larger outside
diameter than the inside diameter of the barrel 16 whereby the piston 62 is in a
compressed state against the inner surface of the barrel 16 when the piston 62 is
inserted into the barrel 16 (p. 9, lines 9-17). The plunger 48, when connected to the
15 piston 62 and moved towards the dispensing end of the barrel 16, causes the
resilient piston 62 to longitudinally stretch to permit the piston 62 to slide towards the
dispensing end of the barrel 16, thereby forcing medication in the medication
reservoir 78 to be ejected from the opening in the dispensing end of the barrel (Fig.
14; p. 9, lines 18-22, and p. 10, lines 1-7). The first end of the plunger 48 is
20 detachably connected to the piston whereby movement of the plunger 48 away from
the piston 62 will cause the first end of the plunger 48 to disconnect from the piston
62 so that the piston 62 remains in the barrel, thereby ensuring that the applicator
may not be reused (p. 9, lines 8-18).

1 Claim 10 depends from claim 8 and describes that the piston 62 has a portion thereof shaped so as to be receivable within the opening formed in the dispensing end of the barrel 16 (Figs. 3-5; p. 7, lines 21-22, and p. 8, lines 1-5).

5 Claim 11 is also dependent from claim 8 and describes that the piston 62 is constructed so as to destruct if an attempt is made to manually move the piston 62 towards the open end of the barrel 16 by applying force against the first end thereof, thereby further ensuring that the applicator may not be reused (p. 10, lines 8-18).

It is believed that each of the claims are allowable and stand by themselves.

10 GROUND OF REJECTION TO BE REVIEWED ON APPEAL

(A) Whether claims 1-3, 8, 10 and 11 are patentable over Ferrer et al. (U.S. Patent No. 6,364,854) under 35 U.S.C. § 103(a).

15 It is the Examiner's position with respect to claims 1 and 8 that Ferrer et al. ("Ferrer") teaches a vaginal medication applicator 10 having a piston 40 slidably mounted on a rod within the main body 20 which is therefore capable of being selectively positioned. It is the Examiner's position that piston 40 fits snugly within section 23 of the main applicator body and provides a closure to the compartment wherein medication is stored. The Examiner also believes that upon application of
20 force to piston 40 by plunger 30, piston 40 is pushed along body 20 towards dispensing end 21 while being longitudinally stretched. The Examiner also believes that Ferrer teaches that the piston and plunger are an effectively unitary impeller means in that when the applicator is manufactured, the piston and plunger are
25 assembled together in an engaged configuration and that therefore, when the

1 impeller means is advanced to propel medication out of the end of the applicator,
both the piston and plunger remain in the barrel to ensure that the applicator is not
reusable. The Examiner admits that Ferrer does not explicitly teach that the plunger,
5 as it exists within an assembled applicator, is detachably connected to the piston in
such a manner as to be capable of being disconnected from the piston, thereby
leaving the piston in the main body portion. The Examiner has concluded that it
would be obvious to one of ordinary skill in the art to modify the applicator of Ferrer to
be manufactured separately from the piston in such a way as to allow the plunger to
10 disconnect from the piston upon completion of use, as these pieces are
manufactured separately and are capable of being assembled separately as an
alternative means of assembling that produces a substantially identical product to the
claimed invention.

15 With respect to claims 2 and 10, the Examiner contends that Ferrer teaches
that the piston 40 fits snugly within portion 23 of body 20 and is thus receivable in
openings 26.

20 With respect to claims 3 and 11, the Examiner contends that since Ferrer
teaches that piston 40 and plunger 30 are assembled together and are constructed in
a complementary manner such that plunger 30 having rib 34 and groove 35 engage
piston 40 via orifice 45 to lock the piston 40 in place, forms an effectively unitary
impeller structure. The Examiner concluded that application of a certain amount of
25 force against the first end of the plunger 30 that is disposed within orifice 45 of piston

1 40 will result in the destruction of the impeller system, thus ensuring that the
applicator cannot be reused.

ARGUMENT

5 (A) Whether claims 1-3, 8, 10 and 11 are patentable over Ferrer et al. (U.S.
Patent No. 6,364,854) under 35 U.S.C. § 103(a).

Appellant does not contend that he is the first person to provide a vaginal
applicator or a pre-fill vaginal applicator. Appellant does believe that he is apparently
the first person to be able to prevent the reuse of a vaginal applicator or a pre-fill
10 applicator by utilizing a structure or design which prevents the flexible piston from
being removed from the barrel of the applicator either by pulling the plunger
outwardly from the barrel after the medication has been dispensed or pushing the
piston forwardly after the medication has been dispensed from the applicator.

15 The Examiner stated in his final rejection that the plunger and piston could be
made in two separate pieces and Appellant does not disagree with that contention
since it is believed that such structures have been previously provided, although
none of the prior art cited by the Examiner apparently discloses such a two-piece
structure. However, there is absolutely no suggestion whatsoever in Ferrer that even
20 if the piston and plunger were made as separate components, that the piston would
remain in the barrel of the applicator upon the plunger being removed from the
applicator. Such a feature is the heart and soul of Appellant's invention. The unique
relationship of the barrel, piston and plunger ensures that the plunger will disconnect
25 from the piston if the plunger is moved outwardly from the barrel upon the medication

1 being dispensed from the applicator. Further, the piston in Appellant's structure will
rupture if an attempt is made to push the piston through the dispensing end of the
applicator.

5 There is not even the most remote suggestion in Ferrer that such a feature or
features as described in the claims under appeal that the plunger will separate from
the piston as claimed or that the plunger will rupture the piston as claimed.

10 Appellant contends that the Examiner has failed to consider the claimed
invention and the prior art "as a whole." MPEP § 2141.02. In determining the
difference between the prior art and the claims, the question under 35 U.S.C. § 103 is
not whether the differences themselves would have been obvious, but whether the
claimed invention as a whole would have been obvious. Stratoflex, Inc. v. Aeroquip
Corp., 713 F.2d 1530, 218 USPQ 871 (Fed. Cir. 1983). A prior art reference must be
15 considered in its entirety, i.e., as a whole, including portions that would lead away
from the claimed invention. W.L. Gore & Associates, Inc. v. Garlock, Inc., 721 F.2d
1540, 220 USPQ 303 (Fed. Cir. 1983).

20 The mere fact that a reference can be modified does not render the resultant
structure obvious unless the prior art also suggests the desirability of the
modification. In re Mills, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990). A
statement that modifications of the prior art to meet the claimed invention would have
been well within the ordinary skill of the art at the time that the claimed invention was
made is not sufficient to establish a *prima facie* case of obviousness without some
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1 objective reason to modify the references. Ex parte Levengood, 28 USPQ2d 1300
(Bd. Pat. App. & Inter. 1993).

5 It is therefore suggested that the Examiner's modification of Ferrer in an
attempt to render Appellant's structure obvious as claimed fails completely. The
problem of reuse of applicators has existed for many years, but now the Examiner
suddenly believes that the Appellant's solution to the problem would have been
obvious under 35 U.S.C. § 103(a) even though the prior art is completely silent as to
any teachings even remotely similar to that claimed in the claims under appeal.

10 It is therefore submitted that the claims under appeal, and each of them, are
patentable. The Ferrer reference does not make independent claims 1 and 8
obvious nor does Ferrer make dependent claims 2 and 3 and dependent claims 10
and 11 obvious.

15 As stated, claim 2 is dependent from claim 1 and further adds limitations
thereto. It is believed that claim 2 is not made obvious under Ferrer under 35 U.S.C.
§ 103(a) inasmuch as claim 2 depends from an allowable claim.

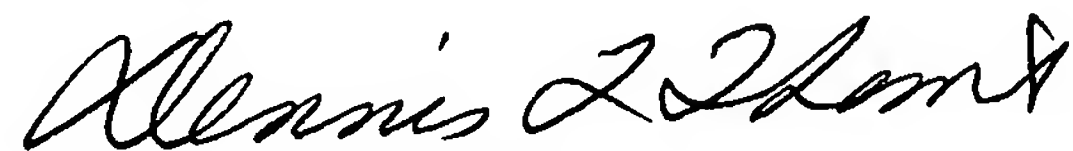
20 Claim 3 is also believed to be independently allowable inasmuch as claim 3
specifically describes that the piston is constructed so as to destruct if an attempt is
made to manually move the piston towards the open end of the barrel by applying
force against the first end thereof as stated in the arguments above.

25 Claim 10 is believed to be separately allowable for the reasons expressed in
support of claims 2 and 8 above.

1 Claim 11 is believed to be separately allowable for the reasons expressed in
support of claim 3 above.

5 Accordingly, the Board is requested to allow claims 1, 2, 3, 8, 10 and 11
inasmuch as it is believed that each claim is not made obvious under Ferrer under 35
U.S.C. § 103(a).

Respectfully submitted,

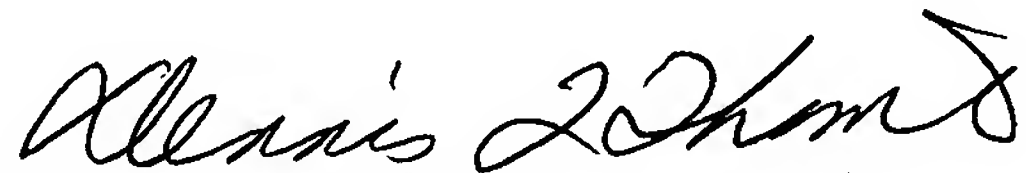


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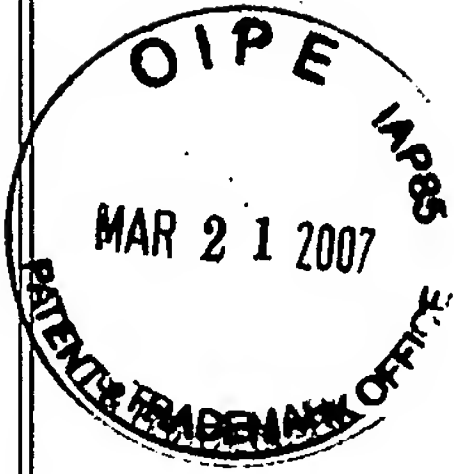
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15 CERTIFICATE OF MAILING

I hereby certify that the original of APPELLANT'S FOURTH AMENDED
APPEAL BRIEF for TROY M. JUST, Serial No. 10/668,785, was mailed by first class
mail, postage prepaid, to the Mail Stop Appeal Briefs-Patent, Commissioner for
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20 DENNIS L. THOMTE



CLAIMS APPENDIX

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1. (Appealed) A pre-fill vaginal applicator, comprising:

a tubular barrel having a dispensing end provided with at least one opening formed therein and an open end;

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said barrel having an inner surface;

a selectively removable closure closing said dispensing end of said barrel;

a resilient piston having first and second ends, selectively slidably positioned in said barrel;

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said piston having an outer surface which is in sealing contact with said inner surface of said barrel to define a medication reservoir between said first end of said piston and said dispensing end of said barrel;

said second end of said piston having an opening extending thereinto which terminates between said first and second ends of said piston;

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an elongated plunger having first and second ends adapted to be inserted into said open end of said barrel whereby said first end thereof may be inserted into said opening in said second end of said piston to detachably connect said plunger to said piston;

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said piston, prior to insertion into said barrel, having a larger outside diameter than the inside diameter of said barrel whereby said piston is in a compressed state against said inner surface of said barrel when said piston is inserted into said barrel;

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said plunger, when connected to said piston and being moved towards said dispensing end of said barrel, causing said resilient piston to longitudinally stretch to permit said piston to slide towards said dispensing end thereby forcing medication in said medication reservoir to be ejected from said opening in said dispensing end of said barrel;

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said first end of said plunger being detachably connected to said piston whereby movement of said plunger away from said piston will cause said first end of said plunger to disconnect from said piston so that said piston remains in said barrel thereby ensuring that the applicator may not be reused.

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2. (Appealed) The applicator of claim 1 wherein said first end of said piston has a portion thereof shaped so as to be receivable within said opening formed in said dispensing end of said barrel.

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3. (Appealed) The applicator of claim 1 wherein said piston is constructed so as to destruct if an attempt is made to manually move said piston towards said open end of said barrel by applying force against said first end thereof, thereby further ensuring that the applicator may not be reused.

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- 4. (Cancelled)
- 5. (Cancelled)
- 6. (Cancelled)
- 7. (Cancelled)

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8. (Appealed) A vaginal applicator, comprising:

a tubular barrel having a dispensing end provided with at least one opening formed therein and an open end;

said barrel having an inner surface;

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a resilient piston having first and second ends, selectively slidably positioned in said barrel;

said piston having an outer surface which is in slidable sealing contact with said inner surface of said barrel to define a medication reservoir between said first end of said piston and said dispensing end of said barrel;

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said second end of said piston having an opening extending thereinto which terminates between said first and second ends of said piston;

an elongated plunger having first and second ends adapted to be inserted into said open end of said barrel whereby said first end of said plunger may be inserted into said opening in said second end of said piston to detachably connect said plunger to said piston;

15

said piston, prior to insertion into said barrel, having a larger outside diameter than the inside diameter of said barrel whereby said piston is in a compressed state against said inner surface of said barrel when said piston is inserted into said barrel;

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said plunger, when connected to said piston and being moved towards said dispensing end of said barrel, causing said resilient piston to longitudinally stretch to permit said piston to slide towards said dispensing end thereby

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forcing medication in said medication reservoir to be ejected from said opening
in said dispensing end of said barrel;

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said first end of said plunger being detachably connected to said piston whereby
movement of said plunger away from said piston will cause said first end of
said plunger to disconnect from said piston so that said piston remains in said
barrel thereby ensuring that the applicator may not be reused.

9. (Cancelled)

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10. (Appealed) The applicator of claim 8 wherein said first end of said
piston has a portion thereof shaped so as to be receivable within said opening
formed in said dispensing end of said barrel.

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11. (Appealed) The applicator of claim 8 wherein said piston is constructed
so as to destruct if an attempt is made to manually move said piston towards said
open end of said barrel by applying force against said first end thereof, thereby
ensuring that the applicator may not be reused.

12. (Cancelled)

13. (Cancelled)

14. (Cancelled)

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15. (Cancelled)

16. (Cancelled)

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EVIDENCE APPENDIX

NONE.

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RELATED PROCEEDINGS APPENDIX

NONE.

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